UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

RENEE BIRNBAUM and AVRUM BIRNBAUM Plaintiffs, v. ETHICON, INC., ETHICON ENDO-SURGERY, INC., JOHNSON & JOHNSON SERVICES, and JOHNSON & JOHNSON, KARL STORZ ENDOSCOPY-AMERICA, INC., KARL STORZ ENDOVISION, INC., KARL STORZ GMBH & CO. KG, VENTION MEDICAL, INC. (F/K/A THE MEDTECH GROUP INC.), VENTION MEDICAL ACQUISITION CO., and VENTION MEDICAL HOLDINGS, INC. Defendants.	**COMPLAINT AND DEMAND FOR JURY TRIAL** **Case No: 17-cv-7024**

Plaintiffs RENEE BIRNBAUM and AVRUM BIRNBAUM ("Plaintiffs"), by and through their undersigned attorneys, hereby sue the named Defendants and allege as follows:

BACKGROUND

1. This lawsuit is a personal injury action against Defendants who were responsible for researching, designing, developing, testing, manufacturing, packaging, labeling, marketing, advertising, promoting, distributing, selling and/or making available certain Laparoscopic Power Morcellators, which are medical devices used during laparoscopic and other types of minimally invasive uterine surgeries.

2. Defendants are part of a family of corporations that focus their business on medical devices and supplies, including medical devices used in abdominal and gynecological surgeries.

3. Defendants' Power Morcellators are defective, and, as a result of their defective nature, individuals, such as the Plaintiff RENEE BIRNBAUM, on whom the Power Morcellators were used and who relied on the Power Morcellators to not be defective, have suffered and/or are

at an increased risk of suffering serious and dangerous side effects, including but not limited to, severe and constant pain and suffering, the dissemination of tissue throughout certain areas of the body, including endometrial tissue and/or cancerous tissue, parasitic fibroids, the need for additional surgery to repair and/or remove disseminated tissue, and/or additional medical therapy to address the dissemination of tissue, as well as other severe and permanent health consequences

4. Plaintiff RENEE BIRNBAUM is one of hundreds of individuals who have been adversely impacted and suffered damages due to the defective Power Morcellators

5. Plaintiffs seek compensatory damages as a result of the defective Power Morcellators that were used in Plaintiff RENEE BIRNBAUM's myomectomy and hysterectomy procedures and which have caused her and/or may cause her to suffer physical pain, mental anguish, medical and/or other expenses.

JURISDICTION AND VENUE

6. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 because complete diversity exists between Plaintiffs, who are citizens of the State of New York, and Defendants, who are incorporated and have their principal places of business.

7. The amount in controversy for the Plaintiffs exceeds $75,000, exclusive of interest and costs.

8. Venue is proper within this District pursuant to 28 U.S.C. § 1391 and it is a judicial district where Defendants are subject to personal jurisdiction in accordance with 28 U.S.C. §§ 1391(a) and (c).

PARTY PLAINTIFFS

9. Plaintiff RENEE BIRNBAUM, is a citizen of the State of New York, County of Nassau, and resides in Cedarhurst, New York.

10. Plaintiff RENEE BIRNBAUM was born on July 29, 1957.

11. In or about July 1997, Plaintiff RENEE BIRNBAUM underwent a laparoscopic myomectomy at Maimonides Medical Center. Upon information and belief, during this surgery, a Power Morcellator manufactured by Defendants was used to tear up and shred Plaintiff RENEE BIRNBAUM'S uterine fibroids. As a result, Plaintiffs RENEE BIRNBAUM'S uterine tissue was disseminated throughout certain areas of her body.

12. In or about February 2007, Plaintiff RENEE BIRNBAUM underwent a laparoscopic hysterectomy at Long Island Jewish Hospital. Upon information and belief, during this surgery, a Power Morcellator manufactured by Defendants was used to tear up and shred Plaintiff RENEE BIRNBAUM'S uterine fibroids as well as her uterus. As a result, Plaintiffs RENEE BIRNBAUM'S uterine tissue was disseminated throughout certain areas of her body.

13. In or about December 2014, Plaintiff RENEE BIRNBAUM underwent a pelvic ultrasound which revealed a pelvic tumor which was excised on February 9, 2015. Ongoing surveillance of her pelvis revealed leiomyosarcoma. Additionally, since December 2014, she has been diagnosed with cancer of the lung and breast which, upon information and belief, is related to the power morcellator used in the aforementioned surgeries.

14. Upon information and belief, as result of the use of Defendants' Power Morcellator in the aforementioned surgeries, Plaintiff RENEE BIRNBAUM has been caused to suffer severe injuries including, but not limited to, constant pain and suffering especially in her pelvic region, spreading and dissemination of uterine tissue resulting in cancer, multiple surgeries and treatments to correct same, and other severe and permanent health consequences.

15. Plaintiffs did not learn that the Power Morcellator that was used in her surgeries caused her injuries until approximately 2017, primarily because Defendants had withheld and/or

concealed the serious health risks associated with the Power Morcellator used in her surgery.

16. Plaintiff, AVRUM BIRNBAUM, is a citizen of the State of New York, County of Nassau, and resides in Cedarhurst, New York.

17. At all relevant times Plaintiff AVRUM BIRNBAUM was the lawful spouse of Plaintiff RENEE BIRNBAUM.

PARTY DEFENDANTS

18. Defendant ETHICON, INC. is a corporation organized under the laws of the State of New Jersey, with its principal place of business at Route 22 West, Sommerville, New Jersey, 08876.

19. Defendant ETHICON, INC has transacted and conducted business in the State of New York.

20. Defendant ETHICON, INC. has derived substantial revenue from goods and products used in the State of New York.

21. Defendant ETHICON, INC. expected or should have expected its acts to have consequence within the State of New York, and derived substantial revenue from interstate commerce within the United States, New York in particular

22. At all relevant times, Defendant ETHICON, INC. was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the Power Morcellators for use in laparascopic and minimally invasive surgeries.

23. Defendant ETHICON ENDO SURGERY, INC. is an Ohio corporation with its principal place of business at 4545 Creek Road, Blue Ash, Ohio, 45242.

24. Defendant ETHICON ENDO SURGERY, INC. has transacted and conducted business in the State of New York.

25. Defendant ETHICON ENDO SURGERY, INC. has derived substantial revenue from goods and products used in the State of New York.

26. Defendant ETHICON ENDO SURGERY, INC. expected or should have expected its acts to have consequence within the State of New York, and derived substantial revenue from interstate commerce within the United States, New York in particular

27. At all relevant times, Defendant ETHICON ENDO SURGERY, INC. was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the Power Morcellators for use in laparascopic and minimally invasive surgeries.

28. Defendant JOHNSON & JOHNSON SERVICES, INC. is a New Jersey corporation with its principal place of business at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

29. Defendant JOHNSON & JOHNSON SERVICES, INC. has transacted and conducted business in the State of New York.

30. Defendant JOHNSON & JOHNSON SERVICES, INC. has derived substantial revenue from goods and products used in the State of New York.

31. Defendant JOHNSON & JOHNSON SERVICES, INC. expected or should have expected its acts to have consequence within the State of New York, and derived substantial revenue from interstate commerce within the United States, New York in particular

32. At all relevant times, Defendant JOHNSON & JOHNSON SERVICES, INC. was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the Power Morcellators for use in laparascopic and minimally invasive surgeries.

33. Defendant JOHNSON & JOHNSON is a New Jersey corporation with its principal place of business at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

34. Defendant JOHNSON & JOHNSON has transacted and conducted business in the State of New York.

35. Defendant JOHNSON & JOHNSON has derived substantial revenue from goods and products used in the State of New York.

36. Defendant JOHNSON & JOHNSON expected or should have expected its acts to have consequence within the State of New York, and derived substantial revenue from interstate commerce within the United States, New York in particular.

37. At all relevant times, Defendant JOHNSON & JOHNSON was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the Power Morcellators for use in laparascopic and minimally invasive surgeries.

38. Upon information and belief, Defendant JOHNSON & JOHNSON owns all of the common stock and other ownership interests of Defendants ETHICON, INC., ETHICON ENDO-SURGERY, INC., and JOHNSON & JOHNSON SERVICES, INC.

39. Upon information and belief, JOHNSON & JOHNSON is either the direct or indirect owner of substantially all the stock or other ownership interests of ETHICON, INC., ETHICON ENDO-SURGERY, INC., and JOHNSON & JOHNSON SERVICES.

40. In doing the acts alleged herein, Defendants ETHICON, INC., ETHICON ENDO SURGERY, INC., JOHNSON & JOHNSON SERVICES, INC. and JOHNSON & JOHNSON (collectively referred to as the "Ethicon Defendants") were acting in the course and scope of such agency, representation, joint venture, conspiracy, consultancy, predecessor agreement, successor agreement, service and employment, with knowledge, acquiescence and ratification of each other.

41. Defendant KARL STORZ ENDOSCOPY-AMERICA, INC. is a corporation organized and/or existing under the laws of the State of California with its principal place of

business at 2151 East Grand Avenue, El Segundo, California 90245.

42. Defendant KARL STORZ ENDOSCOPY-AMERICA, INC. has transacted and conducted business in the State of New York.

43. Defendant KARL STORZ ENDOSCOPY-AMERICA, INC. has derived substantial revenue from goods and products used in the State of New York.

44. Defendant KARL STORZ ENDOSCOPY-AMERICA, INC. expected or should have expected its acts to have consequence within the State of New York, and derived substantial revenue from interstate commerce within the United States, New York in particular

45. At all relevant times, Defendant KARL STORZ ENDOSCOPY-AMERICA, INC. was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the Power Morcellators for use in laparascopic and minimally invasive surgeries.

46. Defendant KARL STORZ ENDOVISION, INC. is a corporation organized and/or existing under the laws of the Commonwealth of Massachusetts with its principal place of business at 91 Carpenter Hill Road, Charlton, Massachusetts 01507.

47. Defendant KARL STORZ ENDOVISION, INC. has transacted and conducted business in the State of New York.

48. Defendant KARL STORZ ENDOVISION, INC. has derived substantial revenue from goods and products used in the State of New York.

49. Defendant KARL STORZ ENDOVISION, INC. expected or should have expected its acts to have consequence within the State of New York, and derived substantial revenue from interstate commerce within the United States, New York in particular

50. At all relevant times, Defendant KARL STORZ ENDOVISION, INC. was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and

distribute the Power Morcellators for use in laparascopic and minimally invasive surgeries.

51. Defendant KARL STORZ GMBH & CO. KG is a corporation organized and/or existing under the laws of the Federal Republic of Germany with its principal place of business at Mittelstrasse 8, Tuttingen, Germany 78532.

52. Defendant KARL STORZ GMBH & CO. KG has transacted and conducted business in the State of New York.

53. Defendant KARL STORZ GMBH & CO. KG has derived substantial revenue from goods and products used in the State of New York.

54. Defendant KARL STORZ GMBH & CO. KG expected or should have expected its acts to have consequence within the State of New York, and derived substantial revenue from interstate commerce within the United States, New York in particular

55. At all relevant times, Defendant KARL STORZ GMBH & CO. KG was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the Power Morcellators for use in laparascopic and minimally invasive surgeries.

56. Upon information and belief, KARL STORZ GMBH & CO. KG is the parent company of KARL STORZ ENDOSCOPY-AMERICA, INC. and KARL STORZ ENDOVISION, INC.

57. Upon information and belief, KARL STORZ GMBH & CO. KG is either the direct or indirect owner of substantially all the stock or other ownership interests of KARL STORZ ENDOSCOPY-AMERICA, INC. and KARL STORZ ENDOVISION, INC

58. Upon information and belief, KARL STORZ GMBH & CO. KG, KARL STORZ ENDOSCOPY-AMERICA, INC. and KARL STORZ ENDOVISION, INC. (collectively referred to as the "Karl Storz Defendants") were the agents, representatives, joint venturers, alter egos, co-

conspirators, consultants, predecessors, successors, servants or employees of each other.

59. In doing the acts alleged herein, Defendants KARL STORZ ENDOSCOPY-AMERICA, INC., KARL STORZ ENDOVISION, INC., and KARL STORZ GMBH & CO. KG were acting in the course and scope of such agency, representation, joint venture, conspiracy, consultancy, predecessor agreement, successor agreement, service and employment, with knowledge, acquiescence and ratification of each other

60. Defendant VENTION MEDICAL, INC. (F/K/A THE MEDTECH GROUP INC.) is a corporation organized and/or existing under the laws of the State of New Jersey with its principal place of business at 6 Century Road, South Plainfield, New Jersey 07080.

61. Defendant VENTION MEDICAL, INC. (F/K/A THE MEDTECH GROUP INC.) has transacted and conducted business in the State of New York.

62. Defendant VENTION MEDICAL, INC. (F/K/A THE MEDTECH GROUP INC.) has derived substantial revenue from goods and products used in the State of New York.

63. Defendant VENTION MEDICAL, INC. (F/K/A THE MEDTECH GROUP INC.) expected or should have expected its acts to have consequence within the State of New York, and derived substantial revenue from interstate commerce within the United States, New York in particular

64. At all relevant times, Defendant VENTION MEDICAL, INC. (F/K/A THE MEDTECH GROUP INC.) was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the Power Morcellators for use in laparascopic and minimally invasive surgeries.

65. Defendant VENTION MEDICAL ACQUISITION CO. is a corporation organized and/or existing under the laws of the State of Delaware with its principal place of business at 1800

Larimer Street, Suite 2200, Denver, Colorado 80202.

66. Defendant VENTION MEDICAL ACQUISITION CO. has transacted and conducted business in the State of New York.

67. Defendant VENTION MEDICAL ACQUISITION CO. has derived substantial revenue from goods and products used in the State of New York.

68. Defendant VENTION MEDICAL ACQUISITION CO. expected or should have expected its acts to have consequence within the State of New York, and derived substantial revenue from interstate commerce within the United States, New York in particular

69. At all relevant times, Defendant VENTION MEDICAL ACQUISITION CO. was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute the Power Morcellators for use in laparascopic and minimally invasive surgeries.

70. Defendant VENTION MEDICAL HOLDINGS, INC. is a corporation organized and/or existing under the laws of the State of Delaware with its principal place of business at 1800 Larimer Street, Suite 2200, Denver, Colorado 80202.

71. Defendant VENTION MEDICAL HOLDINGS, INC. has transacted and conducted business in the State of New York.

72. Defendant VENTION MEDICAL HOLDINGS, INC. has derived substantial revenue from goods and products used in the State of New York.

73. Defendant VENTION MEDICAL HOLDINGS, INC. expected or should have expected its acts to have consequence within the State of New York, and derived substantial revenue from interstate commerce within the United States, New York in particular

74. At all relevant times, Defendant VENTION MEDICAL HOLDINGS, INC. was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and

distribute the Power Morcellators for use in laparascopic and minimally invasive surgeries.

75. Upon information and belief, Defendant VENTION MEDICAL ACQUISITION CO. owns all of the common stock and other ownership interests of Defendant VENTION MEDICAL, INC. (F/K/A THE MEDTECH GROUP INC.).

76. Upon information and belief, Defendant VENTION MEDICAL HOLDINGS, INC. owns all of the common stock and other ownership interests of Defendant VENTION MEDICAL ACQUISITION CO.

77. Upon information and belief, VENTION MEDICAL HOLDINGS, INC., VENTION MEDICAL ACQUISITION CO., and VENTION MEDICAL, INC. (F/K/A THE MEDTECH GROUP INC.) (collectively referred to as the "Vention Defendants") were the agents, representatives, joint venturers, alter egos, co- conspirators, consultants, predecessors, successors, servants or employees of each other.

FACTUAL ALLEGATIONS

78. Laparoscopic Power Morcellators are electrically powered medical tools with spinning blades that shred, grind, and core tissue into smaller pieces or fragments so that the tissue can be removed through small incisions or extraction "ports" in the abdomen.

79. Myomectomies are surgeries that are performed to remove uterine fibroids from a woman's body but not the entire uterus. With conventional myomectomies, when Power Morcellators are not used, the uterine fibroids are removed essentially intact and the uterus is left whole in the woman's body.

80. Hysterectomies are surgeries in which the entire uterus is removed from the woman's body. With conventional hysterectomies, when Power Morcellators are not used, the uterus is removed essentially intact.

81. Over the last few decades, many conventional hysterectomy and myomectomy procedures have been supplanted with electric Power Morcellators to remove uterine fibroids or other tissue, and these Power Morcellators have increasingly replaced traditional open abdominal surgical hysterectomies, myomectomies, and laparotomies.

82. Power Morcellators are designed with a grasper that pulls the tissue up against the sharp, rotating blades, severing the shredded tissue from the rest of the large mass and continuously pulling cut portions of tissue up through the tube.

83. The Power Morcellator's spinning blade shreds the tissue masses at a high velocity and can disperse cellular particles from the shredded tissue throughout the abdomen during surgery.

84. During tissue morcellation, the morcellated fragments can be left in the abdomino-pelvic cavity, or attach to surrounding organs (such as the loops of the bowel), and, if the tissue is cancerous or endometrial, the cancerous or endometrial cells can travel to remote areas of the body through the vasculature or lymphatic system.

85. Once disseminated in the body, morcellated fragments can become implanted in surrounding tissue or organs, and begin to grow.

86. When tissue fragments escape into the abdomino-pelvic cavity and seed in other tissue or organs, complications can arise months or years after the surgery.

87. If the disseminated tissue is cancerous, Power Morcellators can cause the upstaging or worsening of the cancer, changing the stage of the cancer from an early stage cancer into a much higher stage cancer and significantly worsening a woman's prognosis.

88. In addition, certain types of cells with malignant potential may be converted to frankly malignant cells capable of seeding and metastasizing to other parts of the female body.

89. Power Morcellators are Class III medical devices. Class III medical devices are those that operate to sustain human life, are of substantial importance in preventing impairment of human health, or pose potentially unreasonable risks to patients.

90. The 1976 Medical Device Amendments to the Food, Drug and Cosmetics Act of 1938 ("MDA") requires that Class III Medical devices, such as the Power Morcellators, receive premarket approval from the United States Food and Drug Administration ("FDA").

91. The premarket approval process under the MDA obligates the manufacturer to design and implement a clinical investigation regarding the subject device and to submit the results of that investigation to the FDA for review.

92. The premarket approval process under the MDA requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the subject device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredient and properties and of the principle(s) of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing and, when relevant, packaging and installation of such device; samples or devise components required by the FDA; and a specimen of the proposed labeling.

93. The FDA may grant premarket approval only if it finds that there is reasonable assurance that the medical device is safe and effective and must weigh any probably benefit to health from the use of the device against any probable risk of injury or illness from such use.

94. A medical device on the market prior to the effective date of the MDA was not required to undergo premarket approval. Additionally, the MDA provides that a medical device marketed after the MDA's effective date can bypass the rigorous premarket approval process if a

manufacturer represents, and the FDA agrees based on these representations, that the medical device is "substantially equivalent" to a pre-MDA medical device. This exception is known as the "510(k)" process and only requires a manufacturer to notify the FDA, ninety days prior to the medical device's introduction to the market, of its intent to market said medical device. Within this notice, the manufacturer is required to explain the device's "substantial equivalence" to the medical device already on the market.

95. Rather than complying with the FDA's rigorous premarket approval process, Defendants opted to submit their respective Power Morcellators pursuant to the 510(k) process.

96. As such, Defendants were able to manufacture, market and/or sell the Power Morcellators with virtually no clinical or non-clinical trials or FDA review of their Power Morcellators for safety and effectiveness.

97. Defendants failed to appropriately and adequately warn the Plaintiff RENEE BIRNBAUM, her physicians, hospitals, and/or the FDA, of the serious and dangerous risks involved in using their Power Morcellators, including the spread of cancerous tissue.

98. Upon information and belief, Defendants misrepresented the known risks inherent in the use of the Power Morcellators, including the spread of cancerous tissue.

99. Defendants made certain claims that were distributed and circulated to medical and healthcare professions that the Power Morcellators were safe for their intended use during laparoscopic and/or other minimally invasive surgeries.

100. Defendants were careless and negligent in the manufacturing, testing, selling, distribution, merchandising, advertising, marketing, promotion, compounding, packaging, fabrication, warning, analyzing, marketing, and recommendation of the Power Morcellators.

101. By reason of the foregoing, Plaintiff RENEE BIRNBAUM has suffered and/or is

at an extremely high risk of suffering serious and dangerous side effects, including but not limited to constant pain and suffering especially in her pelvic region, spreading and dissemination of uterine tissue resulting in cancer, multiple surgeries and treatments to correct same, and other severe and permanent health consequences.

102. By reason of the foregoing, Plaintiff RENEE BIRNBAUM has been severely and permanently injured and/or has been exposed to risk of severe and permanent injury, and will require more constant and continuous medical monitoring and treatment than prior to the use of Defendants' Power Morcellators.

FRAUDULENT CONCEALMENT, EQUITABLE TOLLING AND DISCOVERY OF CAUSE

103. On or about April 17, 2014, the FDA issued a safety communication discouraging the use of Power Morcellators during hysterectomies or myomectomies for uterine fibroids noting that power morcellation posed a risk of spreading unsuspected cancerous tissue beyond the uterus.

104. Following the issuance of this safety communication, the Ethicon Defendants suspended the sales of their Power Morcellators pending the FDA's investigation. Shortly thereafter, in July 2014, the Ethicon Defendants withdrew their Power Morcellators from the market, and issued letters to healthcare facilities requesting that all Power Morcellators previously purchased be returned to them.

105. Upon information and belief, neither the Karl Storz Defendants nor the Vention Defendants withdrew their products from the market following the FDA's April 2014 Safety Communication.

106. Thereafter, in November 2014, following further investigation into the matter, the FDA updated its April 2014 safety communication to reflect its stronger position that it was affirmatively "warning against" the use of Power Morcellators in hysterectomies or

myomectomies for uterine fibroids.

107. Upon information and belief, neither the Karl Storz Defendants nor the Vention Defendants withdrew their products from the market following the FDA's November 2014 updated Safety Communication.

108. Plaintiffs did not learn that the Power Morcellator that was used in her surgeries could have caused Plaintiff RENNE BIRNBAUM'S injuries as set forth herein until approximately 2017, well after the FDA had issued its November 2014 Safety Communication, primarily because Defendants had fraudulent concealed from her, as well as the public and the FDA, the serious health risks associated with the Power Morcellator used in her surgery.

109. Plaintiffs were unaware of any causal link between the injuries they have suffered and any wrongdoing on the part of Defendants because the Defendants' fraudulently concealed from the Plaintiffs that Power Morcellators could cause the injuries that she suffered following her 1998 and 2007 surgeries.

FIRST CAUSE OF ACTION ON BEHALF OF PLAINTIFFS
(NEGLIGENCE)

110. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

111. Defendants owed a duty to design, manufacture, label, market, distribute, and supply and/or sell a product like the Power Morcellator in such a way as to avoid harm to persons upon whom it was used, including plaintiff, RENEE BIRNBAUM, or to refrain from such activities following knowledge and/or constructive knowledge that such product is harmful to persons upon whom it is used.

112. Defendants owed a duty to warn of the hazards and dangers associated with the use

of its product their Power Morcellators and their associated minimally invasive gynecologic products, for patients such as plaintiff herein, so as to avoid harm.

113. Defendants, acting by and through their authorized divisions, subsidiaries, agents, servants, and employees, were guilty of carelessness, recklessness, negligence, gross negligence and willful, wanton, outrageous and reckless disregard for human life and safety in manufacturing, designing, labeling, marketing, distributing, supplying and/or selling and/or placing into the stream of commerce, minimally invasive gynecologic products, including the Power Morcellator, both generally, and in the following particular respects:

a. failing to conduct adequate and appropriate testing of minimally invasive Gynecologic products, specifically including, but not limited to, products used for uterine morcellation;

b. putting products used for uterine morcellation on the market without first conducting adequate testing to determine possible side effects;

c. putting products used for uterine morcellation on the market without adequate testing of its dangers to humans;

d. failing to recognize the significance of their own and other testing of, and information regarding, products used for uterine morcellation, which testing evidenced such products potential harm to humans;

e. failing to respond promptly and appropriately to their own and other testing of, and information regarding products used for uterine morcellation, which indicated such products potential harm to human;

f. failing to promptly and adequately warn of the potential of the products used for uterine morcellation to be harmful to humans;

g. failing to promptly and adequately warn of the potential for the metastases of cancer when using products used for uterine morcellation;

h. failing to promptly, adequately, and appropriately recommend testing and monitoring of patients upon whom products used for uterine morcellation in light of such products potential harm to humans;

i. failing to properly, appropriately, and adequately monitor the post-market performance of products used for uterine morcellation and such products effects

on patients;

j. concealing from the FDA, National Institutes of Health, the general medical community and/or physicians, their full knowledge and experience regarding the potential that products used for uterine morcellation are harmful to humans;

k. promoting, marketing, advertising and/or selling products used for uterine morcellation for use on patients given their knowledge and experience of such products' potential harmful effects;

l. failing to withdraw products used for uterine morcellation from the market, restrict its use and/or warn of such products' potential dangers, given their knowledge of the potential for its harm to humans;

m. failing to fulfill the standard of care required of a reasonable, prudent, minimally invasive gynecological surgical products engaged in the manufacture of said products, specifically including products used for uterine morcellation;

n. placing and/or permitting the placement of the products used for uterine morcellation, into the stream of commerce without warnings of the potential for said products to be harmful to humans and/or without properly warning of said products' dangerousness;

o. failing to disclose to the medical community in an appropriate and timely manner, facts relative to the potential of the products used for uterine morcellation to be harmful to humans;

p. failing to respond or react promptly and appropriately to reports of products used for uterine morcellation causing harm to patients;

q. disregarding the safety of users and consumers of products used for uterine morcellation, including plaintiff herein, under the circumstances by failing adequately to warn of said products' potential harm to humans;

r. disregarding the safety of users and consumers of the products used for uterine morcellation, including plaintiff herein, and/or her physicians and/or hospital, under the circumstances by failing to withdraw said products from the market and/or restrict their usage;

s. disregarding publicity, government and/or industry studies, information, documentation and recommendations, consumer complaints and reports and/or other information regarding the hazards of the products used for uterine morcellation and their potential harm to humans;

t. failing to exercise reasonable care in informing physicians and/or hospitals regarding the products used for uterine morcellation about their own knowledge

regarding said products' potential harm to humans;

u. failing to remove products used for uterine morcellation from the stream of commerce;

v. failing to test products used for uterine morcellation properly and/or adequately so as to determine its safety for use;

w. promoting the products used for uterine morcellation as safe and/or safer than other comparative methods of lesion removal;

x. promoting the products used for uterine morcellation on websites aimed at creating user and consumer demand;

y. failing to conduct and/or respond to post-marketing surveillance of complications and injuries; and

z. failing to use due care under the circumstances.

114. Defendants knew or should have known that consumers such as the Plaintiff would forseeably suffer injury as a result of Defendants' failure to exercise ordinary care, as set forth above

115. Defendants' actions, by violating statutes, ordinances and/or rules and regulations, constituted negligence per se.

116. Defendants' negligence was the proximate cause of Plaintiff RENEE BIRNBAUM'S injuries, harm, and economic loss which she suffered and/or will continue to suffer.

117. As a direct and proximate result of Defendants' negligence and/or negligence per se, the Plaintiff RENEE BIRNBAUM suffered severe and permanent physical injuries, including but not limited to constant pain and suffering especially in her pelvic region, spreading and dissemination of uterine tissue resulting in cancer, multiple surgeries and treatments to correct same, and other severe and permanent health consequences.

118. The Plaintiff RENEE BIRNBAUM has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. The Plaintiff RENEE BIRNBAUM has lost past earnings and has suffered a loss of earning capacity. The Plaintiff RENEE BIRNBAUM has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. The Plaintiff RENEE BIRNBAUM's injuries and damages are permanent and will continue into the future. The Plaintiffs seeks actual and punitive damages from the Defendants as alleged herein.

119. As a result of the foregoing acts and omissions, the Plaintiff requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

120. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

SECOND CAUSE OF ACTION ON BEHALF OF PLAINTIFFS
(STRICT PRODUCTS LIABILITY - DEFECTIVE DESIGN)

121. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

122. Defendants' Laparoscopic Power Morcellators were expected to, and did, reach the intended consumers, handlers, and persons coming into contact with the product without substantial change in the condition in which they were researched, designed developed, tested, manufactured, packaged, labeled, marketed, advertised, promoted, distributed, sold and/or made available by Defendants.

123. Defendants' Laparoscopic Power Morcellators were defective in design or formulation in that they were not reasonably fit, suitable or safe for their intended purpose and/or their foreseeable risks exceed the benefits associated with their design.

124. Defendants' Laparoscopic Power Morcellators were defective in design or formulation in that they lacked efficacy, posed a greater likelihood of injury and were more dangerous than other available surgical treatment options indicated for the same conditions and uses, including those discussed above.

125. Defendants' Power Morcellators were defective in design or formulation in that when they left the hands of the manufacturers and/or suppliers, the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design, including those discussed above, which had more established safety profiles and a considerably lower risks, or by the provision of reasonable instructions or warnings.

126. Defendants' Laparoscopic Power Morcellators, as designed, posed a substantial and avoidable likelihood of harm and it was feasible to design said products in a safer manner.

127. Defendants' Laparoscopic Power Morcellators were defective in design or formulation in that the dangers associated with their use were unknowable and unacceptable to the average or ordinary consumer.

128. Defendants' Laparoscopic Power Morcellators failed to comply with state and federal standards when sold.

129. At the time of Plaintiff's surgery, the Laparoscopic Power Morcellator was being used for its advertised and intended purpose, and in the manner Defendants intended.

130. As a foreseeable, direct, and proximate result of the aforementioned wrongful acts and omissions of Defendants, Plaintiffs were caused to suffer from the aforementioned

injuries and damages.

131. Due to the aforesaid condition of the Laparoscopic Power Morcellator used on Plaintiff during her surgery, Defendants are strictly liable to Plaintiffs.

132. As a direct and proximate result of the above, the Plaintiff RENEE BIRNBAUM suffered severe and permanent physical injuries, including but not limited to constant pain and suffering especially in her pelvic region, spreading and dissemination of uterine tissue resulting in cancer, multiple surgeries and treatments to correct same, and other severe and permanent health consequences.

133. The Plaintiff RENEE BIRNBAUM has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. The Plaintiff RENEE BIRNBAUM has lost past earnings and has suffered a loss of earning capacity. The Plaintiff RENEE BIRNBAUM has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. The Plaintiff RENEE BIRNBAUM's injuries and damages are permanent and will continue into the future. The Plaintiffs seeks actual and punitive damages from the Defendants as alleged herein.

134. As a result of the foregoing acts and omissions, the Plaintiff requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

135. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

THIRD CAUSE OF ACTION ON BEHALF OF PLAINTIFFS
(STRICT PRODUCTS LIABILITY – FAILURE TO WARN)

136. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

137. Defendants were under an ongoing duty to keep abreast of medically known or knowable information related to their products and to advise clinicians of these risks in a timely manner to ensure the safe use of their product.

138. Defendants failed to adequately warn health care professionals and the public, including Plaintiff and her surgeon, of the following risks associated with the use of their Laparoscopic Power Morcellators, all of which were known or scientifically knowable to Defendants prior to the date on which the Plaintiff underwent surgery in 2007, including, but not limited to:

a. the risk of aggressively disseminating unsuspected malignant tissue beyond the uterus;

b. the device's risk of upstaging a patient's undetected or occult cancer;

c. failing to provide accurate warnings regarding the inadequacy of pre-operative screening for the presence of unsuspected malignant uterine tissue in women;

d. failing to provide accurate rates of the prevalence of unsuspected malignant tissue in women undergoing uterine morcellation; and

e. failing to advise doctors to carefully monitor patients following Laparoscopic Power Morcellator surgery to evaluate for the presence of uterine cancer at an earlier date and to allow for appropriate treatment in the event of such a finding.

139. Defendants' failure to adequately warn Plaintiff and Plaintiff's surgeon of the risks associated with Laparoscopic Power Morcellators prevented Plaintiff and Plaintiff's surgeon from correctly and fully evaluating the risks and benefits of undergoing surgery with the Defendants' devices.

140. Defendants also have known or should have known of the risks associated with the use of specimen containment bags that were not designed for use with a Laparoscopic Power Morcellator, including their potential to perforate or tear during laparoscopic surgery, thereby, creating a risk of tumor spillage and site seeding.

141. Defendants failed to timely include a Black Box Warning regarding the risks of dissemination of occult malignancy and the upstaging of a patient's occult cancer.

142. Defendants failed to timely include a Contraindication that Power Morcellators should not be used in women with tissue of unsuspected, occult, or unknown malignancy.

143. Had Defendants timely and adequately warned of the risks of the Laparoscopic Power Morcellator used during Plaintiff's surgery, such warnings would have been heeded by Plaintiff's surgeon, in that Plaintiff's surgeon would have changed the manner in which he prescribed or selected the Power Morcellator for Plaintiff's surgery, including but not limited to, communicating the risks to the Plaintiff prior to surgery, not using the Power Morcellator, and/or selecting an alternative and safer treatment option for the Plaintiff.

144. If Plaintiff had been adequately warned of the life-threatening risks of the use of the Laparoscopic Power Morcellator, as stated herein, she would have chosen an alternative treatment, one that did not carry the avoidable risks of disseminating and/or upstaging occult cancer and, therefore, would have avoided the injuries described herein.

145. Defendants' failure to adequately warn about the risk of their Power Morcellators was a substantial and contributing factor in causing Plaintiff's injuries.

146. As a direct and proximate result of the above, Plaintiff RENEE BIRNBAUM suffered serious physical injury, pain and suffering and severe mental and emotional distress and economic loss and harm.

147. As a direct and proximate result of the above, the Plaintiff RENEE BIRNBAUM suffered severe and permanent physical injuries, including but not limited to constant pain and suffering especially in her pelvic region, spreading and dissemination of uterine tissue resulting in cancer, multiple surgeries and treatments to correct same, and other severe and permanent health consequences.

148. The Plaintiff RENEE BIRNBAUM has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. The Plaintiff RENEE BIRNBAUM has lost past earnings and has suffered a loss of earning capacity. The Plaintiff RENEE BIRNBAUM has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. The Plaintiff RENEE BIRNBAUM's injuries and damages are permanent and will continue into the future. The Plaintiffs seeks actual and punitive damages from the Defendants as alleged herein.

149. As a result of the foregoing acts and omissions, the Plaintiff requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

150. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

FOURTH CAUSE OF ACTION ON BEHALF OF PLAINTIFFS
(BREACH OF EXPRESS WARRANTY)

151. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

152. In the advertising and marketing of the products used for uterine morcellation, which was directed to both physicians and hospitals and consumers, Defendants warranted that said product or products, were safe for the use, which had the natural tendency to induce physicians and hospitals to use the same for patients and for patients to want to be treated with the same.

153. The aforesaid warranties were breached by Defendants in that the products used for uterine morcellation constituted a serious danger to the user.

154. Plaintiff and her physicians relied upon the express warranties made by the Defendants related to the safety of their power morcellators.

155. As a direct and proximate result of Defendants' breach of warranty, Plaintiff RENEE BIRNBAUM suffered serious physical injury, pain and suffering and severe mental and emotional distress and economic loss and harm.

156. As a direct and proximate result of Defendants' breach of warranty, the Plaintiff RENEE BIRNBAUM suffered severe and permanent physical injuries, including but not limited to constant pain and suffering especially in her pelvic region, spreading and dissemination of uterine tissue resulting in cancer, multiple surgeries and treatments to correct same, and other severe and permanent health consequences.

157. The Plaintiff RENEE BIRNBAUM has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. The Plaintiff RENEE BIRNBAUM has lost past earnings and has suffered a loss of earning capacity. The Plaintiff RENEE BIRNBAUM has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. The Plaintiff RENEE BIRNBAUM's injuries and damages are permanent

and will continue into the future. The Plaintiffs seeks actual and punitive damages from the Defendants as alleged herein.

158. As a result of the foregoing acts and omissions, the Plaintiff requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

159. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

FIFTH CAUSE OF ACTION ON BEHALF OF PLAINTIFFS
(BREACH OF IMPLIED WARRANTY)

160. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

161. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the foregoing products used for uterine morcellation.

162. At all relevant times, Defendants intended that the products used for uterine morcellation be used in the manner that the Plaintiff's surgeons in fact used it and Defendants impliedly warranted the product to be of merchantable quality, safe and fit for such use, and was adequately tested.

163. Defendants breached various implied warranties with respect to the products used for uterine morcellation, including:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the products used for uterine morcellation were safe, and withheld and concealed information about the substantial risks of serious injury and/or death associated with using the products used for uterine morcellation;

b. Defendant represented that the products used for uterine morcellation were as safe

and/or safer than other alternative surgical approaches that did not include the use of the said products, and concealed information, which demonstrated that said products were not safer than alternatives available on the market; and

c. Defendants represented that the products used for uterine morcellation were more efficacious than other alternative surgical approaches and techniques and concealed information, regarding the true efficacy of said products.

164. In reliance upon Defendants' implied warranty, Plaintiff's surgeons used said products as prescribed and in the foreseeable manner normally intended, recommended, promoted, instructed, and marketed by Defendant.

165. Defendants breached their implied warranty to Plaintiff in that said products used for uterine morcellation were not of merchantable quality, safe and fit for their intended use, or adequately tested.

166. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered serious physical injury, pain and suffering and severe mental and emotional distress and economic loss and harm.

167. As a direct and proximate result of Defendants' breach of warranty, the Plaintiff RENEE BIRNBAUM suffered severe and permanent physical injuries, including but not limited to constant pain and suffering especially in her pelvic region, spreading and dissemination of uterine tissue resulting in cancer, multiple surgeries and treatments to correct same, and other severe and permanent health consequences.

168. The Plaintiff RENEE BIRNBAUM has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. The Plaintiff RENEE BIRNBAUM has lost past earnings and has suffered a loss of earning capacity. The Plaintiff RENEE BIRNBAUM has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and

economically injured. The Plaintiff RENEE BIRNBAUM's injuries and damages are permanent and will continue into the future. The Plaintiffs seeks actual and punitive damages from the Defendants as alleged herein.

169. As a result of the foregoing acts and omissions, the Plaintiff requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

170. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

SIXTH CAUSE OF ACTION ON BEHALF OF PLAINITFFS
(FRAUDULENT MISREPRESENTATION AND CONCEALMENT)

171. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

172. Defendants, having undertaken the design, formulation, testing, manufacture, marketing, sale, and distribution of devices used for uterine morcellation owed a duty to provide accurate and complete information regarding said devices.

173. Prior to Plaintiff RENEE BIRNBAUM undergoing her surgeries, Defendants fraudulently misrepresented, that the use of their device for uterine morcellation was safe and effective.

174. Prior to Plaintiff RENEE BIRNBAUM undergoing her surgeries, Defendants fraudulently concealed, that the use of their device for uterine morcellation was not safe and effective.

175. Defendants had a duty to provide plaintiff RENEE BIRNBAUM, physicians, and other consumers with true and accurate information regarding the devices for uterine morcellation it manufactured, marketed, distributed and sold.

176. Defendants made representations and failed to disclose material facts with the intent to induce consumers, including plaintiff, RENEE BIRNBAUM, and the medical community to act in reliance by purchasing and using the uterine morcellator sold by defendant.

177. Plaintiff RENEE BIRNBAUM and the medical community justifiably relied on Defendants' representations and omissions by purchasing and using the Power Morcellator during Plaintiff's hysterectomy and/or myomectomy.

178. Defendants' representations and omissions regarding use of its uterine morcellation devices were a direct and proximate cause of Plaintiff's injuries

179. As a direct and proximate result of the fraud of Defendants, Plaintiff suffered serious physical injury, pain and suffering and severe mental and emotional distress and economic loss and harm.

180. As a direct and proximate result of Defendants' fraud, the Plaintiff RENEE BIRNBAUM suffered severe and permanent physical injuries, including but not limited to constant pain and suffering especially in her pelvic region, spreading and dissemination of uterine tissue resulting in cancer, multiple surgeries and treatments to correct same, and other severe and permanent health consequences.

181. The Plaintiff RENEE BIRNBAUM has endured substantial pain and suffering. She has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. The Plaintiff RENEE BIRNBAUM has lost past earnings and has suffered a loss of earning capacity. The Plaintiff RENEE BIRNBAUM has suffered and will

continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. The Plaintiff RENEE BIRNBAUM's injuries and damages are permanent and will continue into the future. The Plaintiffs seeks actual and punitive damages from the Defendants as alleged herein.

182. As a result of the foregoing acts and omissions, the Plaintiff requires and will require health care and services, and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

183. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

EIGHTH CAUSE OF ACTION ON BEHALF OF PLAINITFFS
(LOSS OF CONSORTIUM)

184. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein

185. Plaintiffs are legally married, and as such, are entitled to the comfort, enjoyment, society and services of one another.

186. As a direct and proximate result of the foregoing, Plaintiff, AVRUM BIRNBAUM, was deprived of the comfort and enjoyment of the services and society of his spouse, the Plaintiff RENEE BIRNBAUM, and have suffered and will continue to suffer economic loss, and have otherwise been emotionally and economically injured.

187. The Plaintiff's injuries and damages are permanent and will continue into the future, and as such, the injuries of the Plaintiff's spouse, AVRUM BIRNBAUM, continue into the future.

188. By reason of the foregoing, Plaintiffs demand judgment against each Defendant, individually, jointly and severally for compensatory damages as well as for punitive damages, attorneys' fees and all such other and further relief as the Court deem proper.

189. By reason of the foregoing, Plaintiff has been damaged as against the Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00).

NINTH CAUSE OF ACTION ON BEHALF OF PLAINTIFFS (PUNITIVE DAMAGES)

190. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint with the same force and effect as if more fully set forth herein.

191. The conduct of Defendants, as set forth herein, above was intentional, willful, wanton, oppressive, malicious, and reckless, evidencing such an entire want of care as to raise the presumption of a conscious indifference to the consequences in that Defendants acted only out of self-interest and personal gain. Such conduct evidences a specific intent to cause harm to Plaintiff as provided. Accordingly, punitive damages should be imposed against Defendants pursuant to and other applicable laws, to punish and deter each Defendant from repeating or continuing such unlawful conduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

(1) Awarding compensatory damages to Plaintiff for past and future damages including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, past and future health care costs, medical monitoring, past and future loss of earnings and/or earning capacity, according to proof, together with interest and costs as provided by law;

(2) Awarding compensatory damages to Plaintiff Spouse for past and future damages for loss of consortium, according to proof;

(3) Punitive and/or exemplary damages for the malicious, wanton, willful, oppressive, and reckless acts of the Defendants who demonstrated a reckless indifference to the rights and safety of the general public and to the Plaintiffs in an amount sufficient to punish Defendants and deter future similar conduct;

(4) Awarding Plaintiffs' attorney's fees;

(5) Awarding Plaintiffs the costs of these proceedings; and

(6) Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury as to all issues

Dated: December 1, 2017

By: */s Virginia E. Anello*

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